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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,955	12/19/2001	Wayne Robert Thomas	IMI-032CP2DV	8377

959 7590 01/12/2004

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/024,955	Applicant(s) THOMAS ET AL.	
	Examin r Patricia A. Duffy	Art Unit 1645	

-- Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 80-92 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 80-92 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The preliminary amendments have been entered. Claims 1-79 have been canceled. Claims 80-92 are pending and under examination.

Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). Applicants are directed to page 33 and the sequences recited therein are not identified by a sequence identifier. Full compliance with the sequence rules is required in response to this office action.

Priority

Applicants are requested to update the current status of all nonprovisional parent applications referenced in the first line of the specification.

Drawings

The drawings in this application are approved by the Draftsperson.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

The information disclosure filed 4-16-02 has been considered. A initialed copy is enclosed.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification lacks antecedent basis for "polymorphic variants", "not cross reactive" antigenic peptides and" protein allergen capable of stimulating T cells specific for *Der f* VII protein allergen, but not *Der p* VII protein allergen".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 86 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the rel vant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

As to claim 86 reciting "polymorphic variant" of a Der f VII protein allergen, the term polymorphic variant is not defined in the specification. As such, given that page 7, lines 8-17 teaches "... it is expected that DNA polymorphisms exist...." and "one skilled din the art will appreciated that these variation in one or more nucleotides (up to about 3-4% of the nucleotides) of the nucleic acids encoding peptides having an activity of Der p VII or Der f VII may exist among individual dust mites due to natural allelic variation." this phrase has been interpreted to be claiming allelic variants of the nucleic acid sequence. The art defines polymorphisms in respect to nucleic acid sequences as different alleles (see Lewin, GENES IV, Oxford University Press, 1990, page 815 (definition) and common usage on paragraph bridging pages 725-726).

As to claim 86, the written description in this case only sets forth the nucleic acid sequence of SEQ ID NO:6 and equivalent degenerative codon sequences thereof as readily conceived from the corresponding amino acid sequence of SEQ ID NO:7. The written description does not describe polymorphic variants (i.e. allelic variant sequences) of the protein of SEQ ID NO:7 or the single DNA allele comprising a DNA sequence of SEQ ID NO:6. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115). The art clearly define alleles or polymorphisms as one of two or more alternative forms of a *gene* occupying the same locus on a particular chromosome..... and differing from other alleles of that locus at one or more mutational sites (see Lewin supra). Thus, the claimed nucleic acid structure of polymorphic variants are not defined within a protein fram work, but rather within a nucleic acid framework. With the exception of th single

allelic DNA sequence SEQ ID NO:6 encoding the protein sequence of SEQ ID NO:7 , the skilled artisan cannot envision the detailed structure of the encompassed allelic polynucleotides and therefore the encoded allelic polypeptides and hence conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself encoding the protein allele is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. Furthermore, In *The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus (i.e. this instant allelic DNA encoding protein alleles). The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules encoding protein molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". There is no written description of any polymorphisms/allelic variants of the single Der f VII nucleotide sequence provided in the specification. Therefore, the specification provides insufficient to support the generic claims as provided by the Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001. Therefore only SEQ ID NO:7, and fragments thereof, meets the written description provision of 35 US 112, first paragraph.

Claims 82-85 and 90-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification fails to provide conception by way of written description for the claimed not cross reactive antigenic peptides and protein allergens capable of stimulating T cells specific for Der f VII protein allergen, but not Der p VII protein allergen. While the specification provides ample support for isolated peptides comprising at least one pitope of a *Der f* VII protein allergen having the amino acid of SEQ ID NO:7, provided that the peptide does not comprise the entire SEQ ID NO:7; the specification at neither page 14, lines 4-7 or 23-25 or page 20, lines 32-34 provides written description support to demonstrate that applicants had conceived at the time of filing of the instant application, the instantly claimed non cross-reactive epitopes. These passages merely provide support for T and B-cell epitopes of SEQ ID NO:7, but not non cross-reactive epitopes as are now claimed. This issue is best resolved by Applicants pointing to page and line number of the specification where written description support for the now claimed invention can be found.

Claims 80-92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 80-92, the claims recite "An isolated nucleic acid encoding..", however a single nucleic acid does not encode a polypeptide. A single nucleic acid is a single nucleotide and this does not encode any polypeptide or even an amino acid. This issue may be resolved by reciting "An isolated nucleic acid sequence encoding..". Additionally, the abbreviation D r f and D r p are confusing b cause they are not traditional abbreviations

of Genus and species. While abbreviations are permitted, the first recitation should be completely spelled out followed by the abbreviation in parenthesis in order to obviate any ambiguity.

As to claim 80, the claim is confusing in the recitation of "the coding region thereof" because it lacks antecedent basis in the claim. Further, coding is relative and the relative positions are not defined by the claim. This issue may be resolved by amending the claim to recite "An isolated nucleic acid comprising the nucleotide sequence as set forth in SEQ ID NO:6 or nucleotide bases 48 through 681 of the nucleotide sequence as set forth in SEQ ID NO:6."

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 86 is rejected under 35 U.S.C. 102(a) as being anticipated by Shen et al (Clinical and Experimental Allergy, 23:934-940, 1993; Reference CA on the PTOL-1449).

The claims are drawn nucleic acids encoding a "polymorphic variant" of the Der f VII protein of SEQ ID NO:7. Shen et al teaches cloning of the *Dermatophagoides pteronyssinus* VII allergen (see figure 3) which is a 90% homologous of the VII allergen of *Dermatophagoides farinae* of SEQ ID NO:7. Since the specification lacks a clear definition of polymorphic variant, the nucleic acid sequence of the prior art encoding the Der p VII protein is deemed to read on the claimed invention. Applicant is reminded that this invention is "by anoth r". As such the claims are anticipated.

Status of the Claims

All claims stand rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 703-305-7555. After January 27, 2004 the examiner can be reached at telephone number 571-272-0855 The examiner can normally be reached on M-F 9:30pm-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on before January 27, 2004 at 703-308-3909, after January 27, 2004 at 571-272-0864. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patricia A. Duffy, Ph.D.
Primary Examiner
Art Unit 1645